

## Message Text

UNCLASSIFIED

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ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 EB-08 COME-00 MED-03  
CIAE-00 INR-07 NSAE-00 /043 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK  
APPROVED BY OES/APT/BMP: WJWALSH, III  
DHEW/PHS/OASH/OIH: RFISCHER  
EUR/NE:CWSCHALLER(INFO)

-----141809Z 074100 /50

P 141711Z APR 77  
FM SECSTATE WASHDC  
TO AMEMBASSY COPENHAGEN PRIORITY

UNCLAS STATE 083886

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, DA

SUBJECT: FDA ADVISORY - IMPROPERLY PLATED SKIN  
ELECTRODES (T-056-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED:

ELECTRODE LEAD ASSEMBLIES WHICH ARE USED ON BODY SKIN  
SURFACES WITH LEADS TO ELECTRO-MEDICAL INSTRUMENTS.

PRODUCT IDENTIFICATION:

MANUFACTURING BRAND IS "NCM" AS SHIPPED. 10 OF 11 DIRECT  
CONSIGNEES USE THE ASSEMBLIES TO PACK WITH ELECTRO-MEDICAL  
INSTRUMENTS AND MAY ALSO DISTRIBUTE THE INDIVIDUAL LEAD  
ASSEMBLIES SEPARATELY, POSSIBLY UNDER THEIR OWN BRAND  
LABELS (WHICH ARE NOT KNOWN AS PRESENT).

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THE ASSEMBLY MODEL (OR PART) NUMBERS WHICH ARE UNDER RECALL  
ARE K2088, K2129, K2130, K2298, AND 77009. ALL OF THESE  
NUMBERS ARE BEING RECALLED AND WERE MANUFACTURED BY THE  
FIRM BETWEEN 10 JUNE AND 31 DECEMBER 1976.

MANUFACTURER/RECALLING FIRM:

NATIONAL CABLE MODELING CORPORATION  
136 S. SAN FERNANDO ROAD  
LOS ANGELES, CALIFORNIA 90031

THE DEFECTIVE CONTACT DISK THAT WAS USED IN THESE ASSEMBLIES WAS CUSTOM SYSTEMS ASSOCIATES, INC. BIO-PHYSICS DIV. 14100 NW SCIENCE PARK DR., PORTLAND OR 97229.

2. REASON FOR RECALL RECOMMENDATION:

THE BRASS DISK WHICH IS PLATED WITH SILVER FOR CONDUCTIVITY AT AN OUTSIDE FIRM AND THEN RETURNED TO NATIONAL CABLE WHERE THE SILVER CHLORIDE IS COMPOUND ON TO THE DISK FORMING THE "SK-22 SILVER CHLORIDE PELLET".

THIS PELLET IS THEN USED IN THE PRODUCTION OF THE LEAD ASSEMBLIES. BECAUSE OF AN INADEQUATE PLATING THICKNESS OF THE SILVER ON THE BRASS DISK THE ZINC FROM THE BRASS REACTED WITH THE SILVER CHLORIDE PRODUCING ZINC CHLORIDE WHICH WAS RESPONSIBLE FOR SKIN IRRITATION AND SKIN BURNS.

3. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF THEY HAVE RECEIVED LETTER DATED 7 MARCH 1977 REQUESTING RECALL OF ELECTRODE-LEAD ASSEMBLIES. ALL RECALLS ARE TO BE RETURNED TO NATIONAL CABLE FOR DESTRUCTION. ANY QUESTIONS CONSIGNEE MAY HAVE WITH RESPECT TO RECALL SHOULD BE DIRECTED TO FIRM (NATIONAL CABLE MODELING CORP.)

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4. FOREIGN CONSIGNEE AS FOLLOWS:

DR. TOM G. BOLWIG  
CODISAN A/S  
PSYCHOCHEMISTRY INST.  
ANEMONEVEJ 60, DK-4000 ROSKILDE  
COPENHAGEN, DENMARK  
VANCE

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 14-Apr-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE083886  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.:CCK  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770130-0058  
**Format:** TEL  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1977/newtext/t19770456/aaaabwup.tel  
**Line Count:** 105  
**Litigation Code IDs:**  
**Litigation Codes:**  
**Litigation History:**  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Message ID:** 8f3023a5-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Retention:** 0  
**Review Action:** RELEASED, APPROVED  
**Review Content Flags:**  
**Review Date:** 12-Nov-2004 12:00:00 am  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 2804303  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - IMPROPERLY PLATED SKIN ELECTRODES (T-056-7)  
**TAGS:** OGEN, ETRD, EIND, TBIO  
**To:** COPENHAGEN  
**Type:** TE  
**vdkgvwkey:** odbc://SAS/SAS.dbo.SAS\_Docs/8f3023a5-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009